



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/815,602

03/23/2001

Javed Naim Agrewala

KUMAP0105US

7206

7590

09/12/2002

Joseph J. Crimaldi
Renner, Otto, Boisselle & Sklar, LLP
Keith Building, 19th Floor
1621 Euclid Avenue
Cleveland, OH 44115-2191

EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 09/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/815,602

Applicant(s)

AGREWALA ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 3, 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1645

DETAILED ACTION

1. Applicants' Response to Office Action, received 26 June 2002, paper #6, is acknowledged.

Claims 1, 2, 3, and 5 have been amended. Claim 4 has been canceled.

2. Claims 1, 2, 3, and 5 are pending and under consideration.

Rejections/Objections Withdrawn/Moot

3. The objection to claim 1 because of informalities is withdrawn in light of the amendment of the claim.

4. The rejection of claim 4 under 35 U.S.C. 112, first paragraph, enablement, is moot in light of the cancellation of the claim.

5. The rejection of claims 1, 2, 3, 5 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in light of the amendment of the claims.

6. The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claim.

7. The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being indefinite for "cancer" and "tumor" as pathogens, is moot in light of the cancellation of the claim.

8. The rejection of claims 1 and 5 under 35 U.S.C. 112, second paragraph, as being indefinite for "with known drugs" and "availability", is withdrawn.

Rejections Maintained

9. The rejection of claims 1, 2, 3, and 5 under 35 U.S.C. 112, first paragraph, enablement, is maintained.

Art Unit: 1645

Applicants argue that upon reading and understanding the application as filed, one of ordinary skill in the art would readily appreciate how to utilize the disclosed method to produce vaccines against a wide variety of diseases.

The examiner has considered applicants' argument, but does not find it persuasive for reasons put forth in the original rejection. Utilizing the terminology "vaccine" imparts criticalities upon the composition of the claims, i.e., the composition must protect a recipient from infection with the infectious agent. As stated in the original rejection, the instant specification provides no data indicating any protective criticalities, merely exposure of *M. tuberculosis* and *S. typhimurium* to drugs and irradiation and culturing in macrophages.

10. The rejection of claims 1 and 5 under 35 U.S.C. 112, second paragraph, as being indefinite for "cancer" and "tumor" as pathogens, is maintained.

Applicants argue that certain cancers, e.g., cervical cancer, have been linked to various intracellular pathogens.

The examiner has considered applicants' argument, but does not find it persuasive. While some cancers may be linked to various intracellular pathogens, it remains indefinite which cancers/tumors applicants are including in the claims.

Conclusion

11. No claims are allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1645

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.


RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER

Art Unit 1645

September 11, 2002